Lipocine Resubmits NDA for Its Oral Testosterone Product Candidate, LPCN 1021, for Treatment of Hypogonadism

SALT LAKE CITY, Aug. 09, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced the resubmission of a New Drug Application ("NDA") for LPCN 1021, its oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.

Lipocine had previously submitted an NDA for LPCN 1021 and received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") in June 2016. The CRL identified a deficiency related to the dosing algorithm for the proposed label. With the goal of addressing this deficiency, the company successfully completed a dosing validation ("DV") study, which confirmed the validity of a fixed dose approach without the need for dose titration to orally administer LPCN 1021. The efficacy results of the DV study, as well as an integrated safety set ("ISS") from all previously conducted clinical trials, including 52-week safety results from the Phase 3 Study of Androgen Replacement ("SOAR") clinical study, form the basis for the NDA resubmission.

"Resubmission of this NDA as planned is an important milestone in bringing LPCN 1021 to patients," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We believe the results from the recently completed DV study address the label-related deficiency identified by the FDA in the CRL. We consider LPCN 1021 to be a differentiated TRT option for treating hypogonadism in men. We anticipate a six-month review by the FDA with a projected PDUFA date in the first quarter of 2018 assuming the FDA acknowledges our submission is a complete response."

About Lipocine

Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in men's and women's health using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1021 was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in Phase 2 testing. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been completed. For more information, please visit www.lipocine.com.

Forward-Looking Statements

This release contains "forward looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding Lipocine's product candidates and related clinical trials and the FDA review process relating to its product candidates, our belief that we have addressed the CRL deficiency, the expected timing of the FDA review process related to our resubmitted NDA, the path to approvability by the FDA of Lipocine's development programs, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including that the FDA will determine there are deficiencies in our resubmitted NDA, the receipt of regulatory approvals, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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